CE Activity Announcement

Practical Training in Compounding Sterile Preparations Certificate

ACPE Activity Number:

- 0204-0000-21-805-H07-P&T
- 0204-0000-21-806-H07-P&T
- 0204-0000-21-807-H07-P&T
- 0204-0000-21-808-H07-P&T
- 0204-0000-21-809-H07-P&T
- 0204-0000-21-810-H07-P&T
- 0204-0000-21-811-H07-P&T
- 0204-0000-21-812-H07-P&T
- 0204-0000-21-813-H07-P&T
- 0204-0000-21-814-H07-P&T
- 0204-0000-21-815-H07-P&T
- 0204-0000-21-816-H07-P&T
- 0204-0000-21-817-H07-P&T
- 0204-0000-21-818-H07-P&T

Release Date: December 1, 2021
Expiration Date: December 1, 2024
Activity Type: Application-based and Knowledge-based
CE Credit Hours (No partial credit): 24 contact hours/14 activities (see below for details)
Activity Fee: $445.00/$545.00 member/non-member

Accreditation for Pharmacists and Pharmacy Technicians

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Target Audience

This activity is intended for pharmacy technicians and pharmacists involved or interested in learning more about compounding sterile preparations and serves as a preparatory course for the PTCB Certified Compounded Sterile Preparation Technician (CSPT) certification exam.

Activity Overview

The online learning activities provide 24 hours of ACPE continuing education for pharmacy technicians and pharmacists, incorporating recorded presentations, readings, video demonstrations, and exercises in curricular modules. The program covers compounding sterile preparation practice standards and regulations, pharmacy calculations, facilities and engineering controls, environmental monitoring, cleanroom personnel behaviors, sterile compounding components and procedures, stability and sterility,

beyond-use date assignment, nonsterile to sterile compounding, hazardous drugs, and the overall compounding process from sourcing through final check or disposal. After completing all of the modules, participants should be proficient in safe and compliant practices for compounding sterile preparations.

Learning Objectives and Schedule of Activities

Activity CE Information	Title, Description, and Learning Objectives
ACPE #: **0204-0000-21-805-H07-P** **0204-0000-21-805-H07-T** CE Hours: **0.75 contact hours (0.075 CEUs)** Activity Type: **Knowledge**	**Title: Introduction to Compounding Sterile Preparations** This activity discusses the guidelines, best practices, standards, and regulations that impact the practice of compounding sterile preparations. **Faculty:** Michael Ganio, Pharm.D., M.S., BCSCP, FASHP **Learning Objectives:** 1. List the standards of practice that apply to sterile compounding in the United States. 2. Identify best practices to ensure sterile compounding safety. 3. Explain the role of the compounder in assuring the safety of compounded sterile preparations.
ACPE #: **0204-0000-21-806-H07-P** **0204-0000-21-806-H07-T** CE Hours: **2 contact hours (0.2 CEUs)** Activity Type: **Application**	**Title: Practical Pharmacy Calculations** This activity covers calculations routinely used by pharmacy personnel when compounding sterile preparations. **Faculty:** DeeAnn Wedemeyer-Oleson, Pharm.D., M.H.A., CPHQ, CPPS **Learning Objectives:** 1. Calculate doses in both weight and volume using proportions with concentrations expressed as fractions, percents, and ratios. 2. Use common conversions to perform sterile compounding calculations. 3. Select quantity of dosage units required to supply an order for a specified time period. 4. Calculate infusion rates. 5. Apply the alligation method to calculate parts of two solutions with different concentrations to compound a solution with a different desired concentration.
ACPE #: **0204-0000-21-807-H07-P** **0204-0000-21-807-H07-T**	**Title: Overview of Compounding Facilities and Engineering Controls**

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Activity CE Information	Title, Description, and Learning Objectives
CE Hours: **1 contact hours (0.1 CEUs)** Activity Type: **Application**	This activity discusses the design, construction, purpose, and maintenance of compounding facilities including the primary and secondary engineering controls and ancillary compounding equipment used in compounding sterile preparations. **Faculty:** Angela Yaniv, Pharm.D., BCSCP **Learning Objectives:** 1. Describe the primary engineering controls used in sterile compounding. 2. Explain the principles of generating a laminar airflow environment in the primary engineering control. 3. Identify the secondary engineering control elements in a clean room environment. 4. Differentiate between a segregated compounding area and a clean room. 5. Discuss essential design elements for a sterile compounding facility. 6. Analyze the advantages and disadvantages of available finish materials.
ACPE #: **0204-0000-21-808-H07-P** **0204-0000-21-808-H07-T** CE Hours: **1.75 contact hours (0.175 CEUs)** Activity Type: **Application**	**Title: Cleanroom Personnel Basics** This activity describes the necessary behaviors and competencies cleanroom staff must master to minimize contamination in cleanroom facilities. **Faculty:** Angela Yaniv, Pharm.D., BCSCP **Learning Objectives:** 1. Identify sources of contamination within the cleanroom. 2. List work behaviors required to prevent the introduction of contaminants into the cleanroom environment. 3. Evaluate appropriate hand hygiene technique. 4. Describe donning and doffing procedures for personal protective equipment used in cleanrooms. 5. Contrast garb and glove requirements and procedures for non-hazardous and hazardous compounding. 6. List core competencies required for sterile compounding personnel. 7. Describe the testing requirements to assess appropriate garbing and aseptic technique. 8. Design a training program to ensure mastery of core competencies by sterile compounding personnel.

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ACPE #: **0204-0000-21-809-H07-P** **0204-0000-21-809-H07-T** CE Hours: **2.25 contact hours (0.225 CEUs)** Activity Type: **Application**	**Title: Materials, Equipment, and Resources for Compounding Sterile Preparations** This activity covers supplies, critical sites, equipment, labels, and references essential for compounding sterile preparations. **Faculty:** Ashley M. Duty, Pharm.D., M.S., BCSCP **Learning Objectives:** 1. List basic compounding supplies. 2. Differentiate between the critical sites and non-critical sites on syringes, needles, vials, and bags. 3. Assess a vial's medication label to determine number of doses and ingredients. 4. Select appropriate compounding materials based on review of medication order. 5. Differentiate between the types of automated compounder pumps used in compounding sterile preparations. 6. Choose the appropriate compounding equipment needed for various situations. 7. Interpret several types of patient medication labels. 8. Create a master formulation record and a compounding record. 9. Use tertiary resources to find necessary drug information.
ACPE #: **0204-0000-21-810-H07-P** **0204-0000-21-810-H07-T** CE Hours: **1.75 contact hours (0.175 CEUs)** Activity Type: **Application**	**Title: Getting Started in Compounding Sterile Preparations** This activity describes dosage forms, small and large volume parenterals, routes of administration, an introduction to parenteral nutrition, high alert medications, and general considerations for automated compounding devices. **Faculty:** Ashley M. Duty, Pharm.D., M.S., BCSCP **Learning Objectives:** 1. Describe the dosage forms, preparation requirements, and routes of administration. 2. Differentiate between small and large volume parenterals. 3. Discuss appropriate routes of administration for compounded sterile preparations. 4. Evaluate medications used in sterile compounding that require special safeguards to reduce the risk of errors. 5. Explain the components and role of parenteral nutrition. 6. Evaluate parenteral nutrition orders and processes.

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	7. Assess automated compounding devices for safety, interoperability, and overall functionality.
ACPE #: **0204-0000-21-811-H07-P** **0204-0000-21-811-H07-T** CE Hours: **2 contact hours (0.2 CEUs)** Activity Type: **Application**	**Title: Stability, Sterility and Beyond-Use Dates** This activity discusses the factors that influence the stability and sterility of compounded sterile preparations, considerations when assigning beyond-use dates, and quality control testing. **Faculty:** Kevin N. Hansen, Pharm.D., M.S., BCPS, BCSCP **Learning Objectives:** 1. List factors that influence beyond-use date assignments for compounded sterile preparations. 2. Describe physical and chemical compatibility criteria for components. 3. Apply USP <797> risk categories to assigning a proper beyond-use date for compounded sterile preparations. 4. Recommend a beyond-use date for a final compounded sterile preparation using evidence-based information.
ACPE #: **0204-0000-21-812-H07-P** **0204-0000-21-812-H07-T** CE Hours: **1.5 contact hours (0.15 CEUs)** Activity Type: **Application**	**Title: Mastering Aseptic Technique** This activity explains “first air,” aseptic technique in horizontal and vertical airflow, reconstituting powders, and appropriate compounding behaviors to prevent or minimize sharps injuries. **Faculty:** Lynda Kiliany, Pharm.D., BCSCP **Learning Objectives:** 1. Define the concept of “first air”. 2. Contrast the location of the direct compounding area in horizontal and vertical airflow. 3. Describe proper methods for disinfecting critical sites on commonly used sterile components. 4. Differentiate workflow steps and best practices associated with compounding in a horizontal laminar airflow workbench and a compounding aseptic isolator. 5. Describe techniques for reconstituting sterile powders. 6. Evaluate placement of hands to prevent disruption of airflow to critical sites when reconstituting powders and withdrawing diluent or medication from vials. 7. Summarize various strategies used to prevent the potential for coring vial stoppers.

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	8. Recommend compounding techniques and behaviors that should be used to prevent and address a sharps injury.
ACPE #: **0204-0000-21-813-H07-P** **0204-0000-21-813-H07-T** CE Hours: **1.25 contact hours (0.125 CEUs)** Activity Type: **Application**	**Title: Medication Cassettes and Other Special Preparations** This activity covers techniques and procedures associated with compounding medication cassettes and other "specials" including epidural, intrathecal, and ophthalmic preparations. **Faculty:** Lynda Kiliany, Pharm.D., BCSCP **Learning Objectives:** 1. Describe techniques for compounding medication cassettes. 2. Calculate doses and infusion rates used with medication cassettes. 3. Explain how to accurately measure components using principles of volumetric accuracy. 4. Describe techniques for compounding 'specials' including epidural, intrathecal, and ophthalmic preparations. 5. Differentiate situations when sterile filtration and/or preservative-free ingredients must be utilized when compounding special administration medications.
ACPE #: **0204-0000-21-814-H07-P** **0204-0000-21-814-H07-T** CE Hours: **2 contact hours (0.2 CEUs)** Activity Type: **Application**	**Title: Non-sterile to Sterile Compounding** This activity describes the regulatory requirements and other unique considerations associated with nonsterile to sterile compounding. **Faculty:** Matthew M. Brown, Pharm.D., DPLA, MLS(ASCP) **Learning Objectives:** 1. Summarize the requirements in section 503A of the Food, Drug, and Cosmetic Act regarding compounding with bulk active pharmaceutical ingredients. 2. Apply USP <797> standards and guidelines to non-sterile to sterile compounding. 3. Differentiate between best practices and regulatory guidance. 4. Discuss key requirements for installation, calibration, and maintenance of equipment used in non-sterile to sterile compounding. 5. Describe validation processes for sterilization equipment. 6. Compare terminal and aseptic sterilization. 7. Calculate endotoxin limits for final products.

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	8. Summarize sterility testing requirements outlined in USP <71>. 9. Explain best practice quality assurance standards for non-sterile to sterile compounding.
ACPE #: **0204-0000-21-815-H07-P** **0204-0000-21-815-H07-T** CE Hours: **2 contact hours (0.2 CEUs)** Activity Type: **Application**	**Title: Maintaining the Cleanroom Environment** This activity discusses the important elements of cleaning and environmental monitoring required to maintain the cleanroom environment. **Faculty:** Majid Tanas, Pharm.D., M.H.A., M.S. **Learning Objectives:** 1. Contrast the roles engineering and administrative controls have in maintaining a cleanroom environment. 2. Discuss principles to consider when implementing design and cleaning processes to ensure and maintain high quality aseptic compounding practices. 3. Differentiate key roles, purpose, and scope of staff working in the cleanroom. 4. Assess the different reagents and processes used to clean primary engineering controls. 5. Describe how to clean primary and secondary engineering controls used for compounding hazardous and non-hazardous preparations to ensure regulatory compliance. 6. Summarize how cleaning regimens impact environmental monitoring results. 7. Design an environmental monitoring performance qualification plan including regularly scheduled monitoring. 8. Recommend appropriate action plans based on personnel and environmental monitoring data.
ACPE #: **0204-0000-21-816-H07-P** **0204-0000-21-816-H07-T** CE Hours: **1.75 contact hours (0.175 CEUs)** Activity Type: **Application**	**Title: Handling Hazardous Drugs: Part 1** This activity covers the scope and requirements associated with USP chapter <800>, developing Assessments of Risk, and how to evaluate your organization's current compliance. **Faculty:** Patricia C. Kienle, R.Ph., M.P.A, BCSCP, FASHP **Learning Objectives:**

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	1. Describe the key requirements of USP <800> Hazardous Drugs – Handling in Healthcare Settings, including limiting risk to personnel, facility design, and safe work practices. 2. Define the scope of USP <800>. 3. Categorize the handling of hazardous drugs in your organization to determine their eligibility for inclusion in your Assessment of Risk. 4. Create an acknowledgement of risk document. 5. List questions relevant to your organization after reviewing USP <800>. 6. Assess your organization's current compliance with USP <800>. 7. Evaluate the organization's storage and compounding areas. 8. List the three types of containment primary engineering controls used for compounding hazardous drugs. 9. List the two types of containment secondary engineering controls used for storage and compounding hazardous drugs. 10. Analyze your organization's most recent certification report. 11. Interpret pressure gradients, air flow direction, and air changes per hour.
ACPE #: **0204-0000-21-817-H07-P** **0204-0000-21-817-H07-T** CE Hours: **2 contact hours (0.2 CEUs)** Activity Type: **Application**	**Title: Handling Hazardous Drugs: Part 2** This activity describes the key responsibilities of the Designated Person, organizing training materials and checklists, and appropriate hazardous drug work practices. **Faculty:** Patricia C. Kienle, R.Ph., M.P.A, BCSCP, FASHP **Learning Objectives:** 1. List the key responsibilities of the Designated Person. 2. Differentiate personal protective equipment used in hazardous drug compounding from that used in non-hazardous compounding. 3. Describe work practice from receiving through compounding. 4. Design a policy and procedure for handling spills. 5. Apply appropriate strategies to achieve compliance identified in gap analyses. 6. Create a checklist that can be used for daily, monthly, and annual monitors for facilities and personnel.
ACPE #: **0204-0000-21-818-H07-P**	**Title: Compounding Process: Sourcing Through Final Check or Disposal**

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0204-0000-21-818-H07-T CE Hours: **2.0 contact hours (0.2 CEUs)** Activity Type: **Application**	This activity discusses the appropriate movement of drugs and supplies used in compounding sterile preparations from receipt through final check or disposal. **Faculty:** Angela Yaniv, Pharm.D., BCSCP **Learning Objectives:** 1. Choose appropriate methods to verify the appropriateness of source ingredients. 2. List cold-chain requirements for refrigerated and frozen products. 3. Identify USP <797> requirements and best practices to introduce materials into a controlled environment. 4. Differentiate storage requirements for hazardous and non-hazardous drugs. 5. Compare cleanroom storage options for high-risk medications, controlled drugs, investigational drugs, non-sterile bulk ingredients, and bulk chemicals. 6. Define preparation labeling guidance and best practices. 7. Apply FDA repackaging guidance to sterile preparations. 8. Differentiate the elements of a master formulation record and a compounding record. 9. Compare the advantages and disadvantages of available final preparation verification methods. 10. Describe the requirements and best practices for controlled substance documentation. 11. Compare storage options for finished compounded sterile preparations prior to administration. 12. Describe requirements and best practices for transport of finished sterile preparations within and outside of the facility. 13. Identify appropriate waste streams for unused compounded sterile preparations, controlled drugs, and used supplies.

Faculty Information

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Relevant Financial Relationship Disclosure

In accordance with our accreditor's Standards of Integrity and Independence in Accredited Continuing Education, ASHP requires that all individuals in control of content disclose all financial relationships with ineligible companies. An individual has a relevant financial relationship if they have had a financial relationship with ineligible company in any dollar amount in the past 24 months and the educational content that the individual controls is related to the business lines or products of the ineligible company.

An ineligible company is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The presence or absence of relevant financial relationships will be disclosed to the activity audience.

The following persons in control of this activity's content have relevant financial relationships:

- Kevin N. Hansen
  - Baxter: speakers bureau, advisory board
  - Omnicell: speakers bureau, advisory board

All other persons in control of content do not have any relevant financial relationships with an ineligible company.

As required by the Standards of Integrity and Independence in Accredited Continuing Education definition of ineligible company, all relevant financial relationships have been mitigated prior to the CPE activity.

Methods and CE Requirements

This online activity consists of a combined total of 14 learning modules. Pharmacists and pharmacy technicians are eligible to receive a total of 24 hours of continuing education credit by completing all 14 modules within this certificate.

Participants must participate in the entire activity, complete the evaluation and all required components to claim continuing pharmacy education credit online at ASHP Learning Center. Follow the prompts to claim credit and view your statement of credit within 60 days of completing the activity.

Important Note – ACPE 60 Day Deadline:
Per ACPE requirements, CPE credit must be claimed within 60 days of being earned. To verify that you have completed the required steps and to ensure your credits have been reported to CPE Monitor, check your NABP eProfile account to validate that your credits were transferred successfully before the ACPE 60-day deadline. After the 60 day deadline, ASHP will no longer be able to award credit for this activity.

System Technical Requirements

System Requirements Courses and learning activities are delivered via your Web browser and Acrobat PDF. Users should have a basic comfort level using a computer and navigating web sites.

View the minimum technical and system requirements for learning activities.